The Impact of the New Data Protection Regulations on Recruitment in Clinical Trials (ImPaCT): A Research Nurse Perspective

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Introduction

The **Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018**[1], referred to as The Health Research Regulation (HRR), was enacted in Ireland in August 2018 following the implementation of the EU General Data Protection Regulation (GDPR)[2]. The Irish interpretation of the GDPR varies from other member states in *that it makes Explicit Consent a requirement for participation in clinical research*. This requirement for Explicit Consent may be avoided in rare or exceptional circumstances by a successful application to the Health Research Consent Declaration Committee (HRCDC).

The implementation of the HRR has meant that many participants already engaged in research before the 8th August 2018 had to be re-consented to a GDPR-compliant consent form, unless they made an application to the HRCDC. Additionally, for any new research commenced after the 8th August 2019, the consent forms used had to meet the requirements set out in the GDPR Article 13. This has increased the burden of work for researchers involved in all aspects of clinical research, in particular research nurses who have had to re-consent participants to ongoing research studies.

The introduction of the HRR has led to uncertainty surrounding its' implications and has generated a broad discussion amongst clinical research staff regarding its impact. Given that these new and updated regulations have a significant impact on our day to day work activities, the ImPaCT survey aimed to gain a broader insight into the challenges facing research nurses as a result of the GDPR and the HRR 2018.

Aims

1. To determine the impacts that the GDPR and HRR 2018 have on recruitment to clinical trials.
2. To assess the awareness of research nurses about GDPR and the HRR 2018.
3. To ascertain whether any studies have been suspended or delayed due to the introduction of the GDPR & HRR 2018.
4. To get an overview of any positive or negative experiences associated with the introduction of the GDPR & HRR 2018.

Methods

This study received approval from the UCC Social Research Ethics Committee.

All research nurses within the Irish Research Nurses Network (IRNN) were invited to participate via email and their newsletter. The email briefly outlined the research and contained a link to an online Information Leaflet/Consent Form and a survey consisting of 8 questions. Respondents had to indicate that they were willing to consent before completing any of the questions. The respondents were informed that all responses were fully anonymous – i.e. no identifiable information or IP addresses were collected.

Questions in ImPaCT Survey:

1. How long have you worked in clinical research?
2. Do you know when the new GDPR guidelines came into effect?
3. Do you know when the Health Research Regulations came into effect?
4. Has local interpretation of the guidelines changed how you recruit patients?
   If yes, how?
5. Has local interpretation of guidelines changed how you consent patients?
   If yes, how?
6. Have the new guidelines caused suspended recruitment to any of your trials?
7. Have you found the new guidelines helpful for recruiting patients?
   If 'Yes', please comment; If 'No', please give reasons.
8. Do you have any other opinions on the introduction of the GDPR/HRR 2018?

Results

In total 31 research nurses responded to the survey. The median length of time respondents had worked in research was 8.5 years. 87.1% were aware of when the GDPR was implemented, and 70.9% knew when the HRR 2018 came into effect.

- When asked if the guidelines changed how participants are recruited, 25% mentioned that Participant Information Leaflets were more complex.
- When asked if the guidelines changed how participants are consented, 46.2% reported increased time to consent participants
- 31.3% mentioned that the Irish HRR were more prohibitive when compared to European interpretation of the GDPR

Results continued

	Yes %	No %	Not Answered %
Do you know when the new **GDPR** guidelines came into effect?	87.10	9.68	3.23
Do you know when the new **Health Research Regulations** came into effect?	70.97	25.81	3.23
Has local interpretation of the guidelines changed how you **recruit** patients?	61.29	35.48	3.23
Has local interpretation of guidelines changed how you **consent** patients?	48.39	38.71	12.90
Have the new guidelines caused suspended recruitment to any of your trials?	29.03	54.84	16.13
Have you found the new guidelines helpful for recruiting patients?	9.68	74.19	16.13

Table 1: Responses to yes/no questions in survey

Perspectives

We've regulated ourselves into a corner and are making Ireland a very unattractive place to do research.

Multinational sponsors are often confused as the rules appear to be much stricter in Ireland in adhering to GDPR.

Causing anxiety and increases workload re-consenting patients.

Most hospitals will not allow their DPO to be named which leads to delays in finalising the consents for submission to ethics.

Unintelligible nonsense.

Conclusions

- It is evident from the responses to this survey that there is still a low level of understanding amongst research nurses surrounding the Regulations.
- The introduction of the HRR 2018 seems to have had a negative impact on trial recruitment and conduct from the research nurses' perspective.
- A proportion of nurses indicated that it resulted in suspended trial recruitment.
- In conclusion, it is paramount that all staff are trained appropriately regarding the implications of the Regulations.

Recommendations

- Provide regular training sessions in GDPR and the HRR 2018 to research nurses.
- Greater understanding could assist with preventing delays or suspensions to studies as a result of the HRR 2018.
- Provide more forums in the research community to engage research nurses in the interpretation of the HRR 2018 in the future.
- Conduct larger study with other research staff to determine further impacts of the data protection Regulations of clinical trial recruitment

References

1. http://www.irishstatutebook.ie/eli/2018/si/314/made/en/pdf *Accessed 04-Nov-2019*
2. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

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